Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the efficacy of surfactant administration by laryngeal mask airway (LMA) and endotracheal intubation in neonatal respiratory distress syndrome

Protocol summary

Summary

In a randomized clinical trial 70 preterm neonates with gestation age 33-37 weeks that diagnosed as respiratory distress syndrome and need treatment with surfactant will randomly allocate to two groups. Thirty five neonates receive surfactant via endotracheal tube and 35 with laryngeal mask. Then patients will be extubated. Premedication and management with fentanyl is same in both groups. We follow patients with respect to need for FiO2 to maintain normal O2 saturation and need for intubation and assisted ventilation during the first 3 days after surfactant therapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201411183915N12**
Registration date: **2014-11-28, 1393/09/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-11-28, 1393/09/07

Registrant information

Name

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Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-11-21, 1393/08/30

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of surfactant administration by laryngeal mask airway (LMA) and endotracheal intubation in neonatal respiratory distress syndrome

Public title

Comparing the efficacy of surfactant administration by laryngeal mask airway (LMA) and endotracheal intubation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: gestation age 33-37 weeks; confirmed diagnosis of respiratory distress syndrome according to clinical and radiological findings; treatment with surfactant Exclusion criteria: major congenital anomalies; congenital heart disease; cranio-facial anomalies; esophageal atresia; birth weight less than 1800 grams

Age

From **1 day** old to **3 days** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Tabriz University of Medical Sciences

Street address

Golghasht street

City

Tabriz

Postal code

Approval date

2014-11-10, 1393/08/19

Ethics committee reference number

93116

Health conditions studied

1

Description of health condition studied

Respiratory Distress Syndrome

ICD-10 code

p22

ICD-10 code description

Respiratory distress syndrome

Primary outcomes

1

Description

Reduced needed FiO2 to maintain adequate oxygenation

Timepoint

Before and one hour after surfactant therapy

Method of measurement

Determination of needed Fio2 in blender and by pulse oxymetry

Secondary outcomes

1

Description

Need for intubation and assisted ventilation

Timepoint

Till 3 days after treatment

Method of measurement

Pulse oxymetry and blood gas analysis

Intervention groups

1

Description

Intervention group: administration of surfactant 4cc/kg survanta in 4 divided dose via laryngeal mask after receiving 1-2 µ/kg intravenous fentanyl

Category

Treatment - Drugs

2

Description

Control group: administration of surfactant 4cc/kg survanta in 4 divided dose via endotracheal tube after receiving 1-2 µ/kg intravenous fentanyl

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al Zahra Hospital

Full name of responsible person

Dr Reza Radfar

Street address

South Artesh Street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Vice Chancellor for Tabriz University of Medical Sciences

Full name of responsible person

Dr Farhoodi

Street address

Golgasht street

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Vice Chancellor for Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty